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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,462	05/08/2001	Robert Ian Lechler	2292/OH795	8594
7590	07/17/2006		EXAMINER	
King & Spalding 191 Peach Tree Atlanta, GA 30303			Ouspenski, Ilia I	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,462

Applicant(s)

LECHLER ET AL.

Examiner

ILIA OUSPENSKI

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-7 and 31-52 is/are pending in the application.
- 4a) Of the above claim(s) 7,31-34,51 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,35-39,41-47 and 50 is/are rejected.
- 7) ☒ Claim(s) 40,48 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/11/2006.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment/remarks, filed 05/11/2006, are acknowledged.

Claims 2 – 4 and 8 – 30 have been cancelled previously.

Claims 1, 38, 46, and 49 have been amended.

Claims 1, 5 – 7, and 31 – 52 are pending.

Claims 7, 31 – 34, and 51 – 52 have been withdrawn from consideration by the Examiner as being drawn to nonelected inventions.

Claims 1, 5 – 6, and 35 – 50 are under consideration in the instant application.

2. This Office Action will be in response to applicant's amendment and arguments, filed 05/11/2006.

The rejections of record can be found in the previous Office Action, mailed 12/08/2005.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

It is noted that New Grounds of Rejection are set forth herein.

3. The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

4. Applicant's IDS, filed 05/11/2006, is acknowledged, and has been considered.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "B7/CD28 interactions," because it is unclear whether the phrase is intended to mean "interactions between B7 and CD28 molecules," or "interactions of B7 molecules or CD28 molecules."

Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claim 1 is rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment asserts that no New Matter has been added and points to the specification at page 2, lines 12 – 14, and page 3, lines 8 – 10, for support for the newly added limitation "activation of xenoreactive T-cells in a recipient through modulation of B7/CD28 interactions." However, the specification does not appear to provide an adequate written description of this limitation.

The specification at page 3 discloses "T-cell mediated rejection of a xenotransplanted organ by blocking the delivery of co-stimulatory signal 2 in order to prevent the activation of xenoreactive T-cells in the recipient," while the disclosure at page 2 provides that "signal 2 is supplies by the interaction between B7 molecules [...] and CD28."

This disclosure is not seen as providing sufficient support under 35 USC 112, first paragraph, for the generic recitation of "modulation," which encompasses both upregulation and downregulation, because the specification only appears to provide support for "blocking" the interaction between B7 and CD28 molecules.

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

9. Claim 1 stands rejected under **35 U.S.C. 112, first paragraph**, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, essentially for the reasons of record.

Applicant's arguments have been fully considered but have been found only partially convincing. In view of applicant's arguments, the rejection of record has been modified, to more specifically define the scope of enablement:

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a biological reagent comprising porcine CTLA-4 that inhibits rejection of a porcine xenotransplanted organ, does not reasonably provide enablement for a generically recited biological reagent comprising porcine CTLA-4 that inhibits rejection of a xenotransplanted organ.

It is noted that while claim 1 limits the scope of the CTLA-4 molecules to those of porcine origin, the origin of the "xenotransplanted organ" is not specified, and thus encompasses any donor species.

Applicant argues the preferential binding of porcine CTLA-4 to pig B7 molecules "is at the heart of the present invention." This is not found persuasive, because, as noted above the claim is not limited to interaction of porcine CTLA-4 with porcine B7 molecules on the transplanted organ, since the source of the organ encompasses any donor species.

Further, Applicant provides references of Vaughn et al. (J. Immunol., 2002, 165: 3175 – 3181) and Mirenda et al. (Diabetes, 2005, 54 : 1048 – 1055) as supporting the use of graft-specific CTLA-4 molecules in xenotransplantation. Again, although these references appear to be supportive of the use of porcine CTLA-4 in combination with porcine transplants, they do not provide sufficient evidence of enablement commensurate with the scope of the claim as presently recited. The references have been cited of record by the examiner, as relevant to patentability of the instant claims.

Therefore, the rejection of record is maintained essentially for the reasons of record, as it applies to the amended claim. The rejection or record is incorporated by reference herein, as if reiterated in full.

10. Claims 1, 5, 6, 35 – 38, 41 – 46, and 50 stand rejected under **35 U.S.C. 102(e)** as being anticipated by Larsen et al. (US Patent 5,916,560; see entire document), for the reasons of record.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the instantly claimed invention is distinct from the teachings of Larsen et al., because Larsen et al. teach using CTLA-4 from the same species as the transplantation host, while the instant claims are allegedly directed to xenograft-specific inhibition.

This is not found persuasive, because Applicant argues limitations which are not claimed.

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Contrary to Applicant's assertion, the instant claims only require that the transplant be derived from a species distinct from the host species (as implied by the use of the term "xenotransplanted"), and that the CTLA-4 be of porcine origin; the instant claims, as presently recited, do not require that the transplant be of porcine origin.

Thus, the teachings of Larsen et al. regarding the use of CTLA-4 in xenotransplantation (e.g. column 6 lines 29 – 33) in various host species, including pigs (i.e. using porcine CTLA-4 for transplantation into pig donors; e.g. column 8 lines 40 – 45), meet the limitations of the instant claims.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

11. Claims 5, 35, 39, 41, 43, and 47 stand rejected under **35 U.S.C. 103(a)** as being unpatentable over Larsen et al. (US Patent 5,916,560; see entire document) in view of Strom et al. (US Patent 6,165,476; see entire document), for the reasons of record.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the combination of cited references does not render the invention obvious, because the Larsen et al. do not teach using porcine CTLA-4 for xenotransplantation.

This argument has been addressed in section 9 supra, and has not been found persuasive.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

12. Claims 40, 48, and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Conclusion: claims 40, 48, and 49 appear to be directed to allowable subject matter.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.

Patent Examiner

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July 12, 2006


PHILLIP GAMBEL, PH.D. JD
PRIMARY EXAMINER

7/12/06

Flu/af